REMARKS

Claims 1 – 35 are pending. Claim 4 has been amended to recite the more grammatically conventional term "plastic" rather than "plastics." Claims 33 and 35 have been amended to render the rejection for indefiniteness moot.

Rejections Under 35 USC § 102(b)

Claims 32-35 are rejected under 35 USC § 102(b) as being anticipated by Daniel (US 4,276,491). Applicant contends that the Examiner has misread Daniel. Daniel does not in fact disclose an ultrasound device operating at a high frequency greater than 20 MHz having a focal length capable of focusing on the macular region of the eye. Instead, Daniel discloses a device having a "focus of approximately 5.5 mm" (column 5, lines 41-42) with "a resonant operating frequency of 3 MHz" (column 5, lines 37-38). Nowhere does Daniel disclose a deeper focus length at a higher frequency

As evidence of a frequency higher than 3 MHz, the Examiner points to a section of Daniel discussing the field of the invention (*i.e.* the prior art). This section of Daniel, column 1, lines 8-15, is reproduced below.

> Ultrasounds, or ultra high-frequency sound waves, are being used more and more routinely to examine the interior of a body painlessly, and with a minimum of risk and expense. The conventional pulse echo technique, based on the similar technique used in sonar systems, involves emitting a short pulse of ultrasonic energy, typically in the 1-30 MHz frequency range, into a patient. Any acoustic impedance discontinuity reflects some of the energy in the form of an echo.

Applicant contends this does not relate to Daniel's device, which in any case, only discloses a focal length of 5.5 mm, which is not a length that would be capable of reaching the macular region of the eye. Therefore, Daniel does not teach all of the recitations of claims 32-35 and this rejection should be withdrawn.

Rejections Under 35 USC § 103(a)

Claims 1, 2, 5, 10, 12, 13, 17-19, and 27-35 are rejected under 35 USC § 103(a) as being obvious over Silverman (US 5,776,068) in view of Chapelon (US 5,666,954). Applicant traverses this rejection for the following reasons. (The following arguments also apply to rejection of Claims 1, 2, 5, 10, 12, 13, 17-19, and 27-35 under 35 USC § 103(a) as being obvious over Silverman (Ophthalmology 1965) in view of Chapelon (US 5,666,954)).

In order to establish a *prima facie* case of obviousness, the Examiner must establish three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the elements of the claim. The teaching or suggestion to make the claimed combination or the reasonable expectation of success must both be found in the prior art and not based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Applicant contends that the Examiner has not established any of these three criteria.

As discussed in the Response filed on December 27, 2002, Silverman provides no motivation or suggestion with respect to ultrasound examination of the *posterior* section of the eye. Nor does Silverman provide a reasonable expectation of success for the examination of the posterior section of the eye. Silverman used an already available 50 MHz PVDF transducer focused at about 10 mm to examine the anterior of the eye. (See column 3, lines 57-60). Silverman is silent on the possibility of examining the posterior section of the eye and, therefore, does not provide motivation or a reasonable expectation of success of an ultrasound transducer having a focal length of about 20 to 25 mm.

Chapelon does not remedy the defects of Silverman. The Examiner states at page 3 of the Office Action dated July 16, 2003 that "Chapelon is evidence that one of ordinary skill in the art of the field of ultrasound eye scanning would recognize the benefit of using a transducer having a focal length in the range of 20 mm to 70 mm since deep penetration is required for imaging the posterior wall (e.g. the macular) of the eye." This argument is flawed for several reasons.

First, Chapelon is a therapeutic endo-rectal probe for destroying tumor tissue in the prostrate gland. Applicants contend that this invention is sufficiently different from the field of eye examination that it would not provide motivation to modify Silverman. Moreover, applicant contends that is non-analogous art.

Second, the focal length of the transducer of Chapelon while having a range of 20 mm to 70 m, is "ideally" 50 mm. (See Chapelon, column 5, lines 15-18). A focal point range spanning 50 mm (between 20 mm to 70 mm), ideally at a 50 mm distance, does not suggest a focal length range spanning about 5 mm, at a 20 mm to 25 mm length. Applicant contends that Chapelon does not suggest the "focal length of about 20 mm to about 25 mm" recited in the claims of the present invention.

Third, the Chapelon reference discloses an imaging transducer that operates at a frequency lying in a range from 3 MHz to 7 MHz. (See Chapelon, column 5, lines). There is nothing in the combination of Silverman and Chapelon establishing that one of skill in the art would have a reasonable expectation of success in the combination of the 50 MHz transducer, with a focal length 10 mm, as described by Silverman at column 3, lines 57-59, with the transducer of Chapelon, which has an ideal focal length of 50 mm and "operates at a frequency lying in a range from 3 MHz to 7 MHz," as described by Chapelon at column 5, pages 63-65. As the applicant has previously argued it was not thought possible, prior to the present invention, to an ultrasound transducer to have a frequency greater than 20 MHz and a focal length of about 20 mm to about 25 mm.

Fourth, the Examiner failed to view the invention as a whole. The Examiner is selecting from two references with different teachings, but with no evidence of motivation to combine or a reasonable expectation of success. The proper analysis for obviousness is to view the invention as a whole, not in terms of each of its features.

Fifth, the Examiner's analysis ignores the numerous references submitted by applicant that evidence one of skill in the art would not have been motivated to arrive at the present invention and the skilled artisan would not have had a reasonable expectation of success of the outcome of the present invention. Moreover, applicant submits that these articles also evidence a teaching away from the present invention.

For example in Chapter 8 *Ultrasound of the Eye and Orbit* (2nd ed., 2002) (reference A1 of the IDS submitted April 30, 2003), the authors consistently mention that ultrasound examination is limited to the anterior of the eye. At page 223, the authors state that the maximum penetration for 10MHz is about 50 mm, while for a 60 MHz, the penetration is only 5 mm. In the second paragraph of 226 the authors state that "[e]xamination of structures such as the posterior pole of the eye is not possible at the present time" and at page 234, "UBM presents a new method of imaging the anterior segment of the eye at high resolution." With respect to claims 4 and 11, which have recitations related to a plastic material, the first paragraph of page 226 states that a plastic cover defeats the purpose of doing examinations at a high frequency. Other references of record have the following teachings:

Pavlin, "Ultrasound Biomicroscopy in assessment of anterior scleral disease, Am J Ophthalmology. 1993 ; 116:628-635" (reference A2 of the April 30, 2003 IDS)

"Penetration is limited to 4 to 5 mm, which is adequate to display the majority of the anterior segment of the eye." (page 629)

"Penetration is not adequate to cross the globe to examine the posterior sclera." (page 629)

"The area of sclera imaged is presently confined to the anterior globe, that is, that part of the globe which can be approached directly over the surface." (page 633)

Silverman: "Three Dimensional High Frequency Ultrasonic Parameter Imaging of Anterior Segment, Ophthalmology, 1995; 102:837-843" (of record)

"50 to 100 MHz range currently are being used to examine the anterior segment." (page 837)

"(the use of high frequency transducer) is limited in applicability due to the rapid increase in acoustic attenuation with increasing frequency. The anterior segment is a special case... High frequencies thus can be used to the greatest advantage for imaging anterior segment structures. (page 838)

Pavlin : "Subsurface ultrasound microscopic imaging of intact eyes" Ophthalmology 1990 ; 97 : 241-250 (of record)

"These devices are capable of producing images to a depth of 4 mm." (abstract)

"higher frequency ultrasound results in greater resolution and more accurate measurement, but at the expense of decreased penetration." (page 244)

"Tissue penetration is confined to approximately 4 mm." (page 244)

"It is unlikely that penetration can be increased enough to image the posterior globe." (page 250)

Ultrasound backscatter microscopy of the eye in vivo IEEE ultrasonic symposium : proceedings 1481-1484 (90CH2938-9) 1990 (reference A3 of the April 30, 2003 IDS)

"Microscopic images of the normal structures of anterior segment..." (page 1481)

"a maximum depth of penetration of approximately 5 mm." (page 1481)

Ultrasound Biomicroscopy of anterior structures in normal and glaucomatous eyes, Am. J. Ophthalmol. 1992; 113:381-389 (reference A4 of the April 30, 2003 IDS)

"In general, higher frequency transducers are used for fine resolution of more superficial structures and lower frequency transducers are used when depth of penetration is important." (page 1)

"Tissue penetration is approximately 4mm." (page 1)

Pavlin & Foster, "Ultrasound Biomicroscopy of the eye ; basic physics of high-frequency ultrasound imaging. 1995 Springer-Verlag New-York: 13-15" (reference A4 of the April 30, 2003 IDS)

"the penalty to be paid for this increase in resolution is loss of penetration" (page 14)

"For the 60 MHz system, penetration is only 5 mm" (page 14)

Plot of penetration versus frequency under realistic conditions. Increased resolution at elevated frequencies is accompanied by reduced penetration due to increased losses in the tissues... only 5 mm can be penetrated at 60 MHz (page 14)

"Because losses due to attenuation increase almost linearly with frequency, the total imaging depth is significantly reduced, leading to fields of view of 4-5 mm." (page 15)

Claims 14-16 and 20-22 are rejected under 35 USC § 103(a) as being obvious over Silverman (US 5,776,068) in view of Chapelon (US 5,666,954), and in further view of Zeimer (US 4,883,061). The Examiner has stated throughout the Office Action dated July 16, 2003 that Zeimer is related to "ultrasound method." Applicant urges that this is simply not true.

As applicant has argued before, Zeimer uses a laser to measure the thickness of eye components, not an ultrasound method. There is simply no discussion of ultrasound or even sound imaging in Zeimer. A key word search of text of Zeimer for the terms "sound," "ultra," or "sonic" (either alone or with another word) showed that these terms are not present in Zeimer.

Claims 3, 4, 6-9 and 23 are rejected under USC §103(a) as being unpatentable over Silverman et al in view of Coleman et al (US 5,331,962) or Reinstein et al. (US 5,293,871). Applicant traverses this rejection.

This rejection is premised upon the Examiner's argument that Silverman and Chapelon teach all of the recitations of the present claims. As described above, applicant urges that Silverman and Chapelon do not teach or suggest all or the recitations of the claims. Moreover, these two references, either alone or in any combination with Coleman or Reinstein, neither teach or suggest all of the recitations of the claims, motivate one of ordinary skill in the art to combine these references, or provide a reasonable expectation of success of the present invention.

Again these references are only directed to ultrasonic biometer images that had only been obtained on the corneal layer, *i.e.*, the anterior segment of the eyeball. Therefore, the combination of any of these references does not teach every element of the claims nor provides a reasonable expectation of success nor a suggestion of how one could use ultrasound to examine the posterior of the eye.

The Examiner's argument that Zeimer is combinable with Silverman and Chapelon is based on the erroneous assertion the Zeimer is directed to a laser device. As this is not true, the Examiner's argument must fail. Furthermore, applicant submits that an ultrasound device, which uses sound for

imaging, is completely different from a laser, which uses beams of light to quantitatively determine retinal depth.

Respectfully submitted,

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Should additional fees be necessary in connection with the filing of this paper, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge Deposit Account No. 19-0741 for any such fees; and applicant(s) hereby petition for any needed extension of time.

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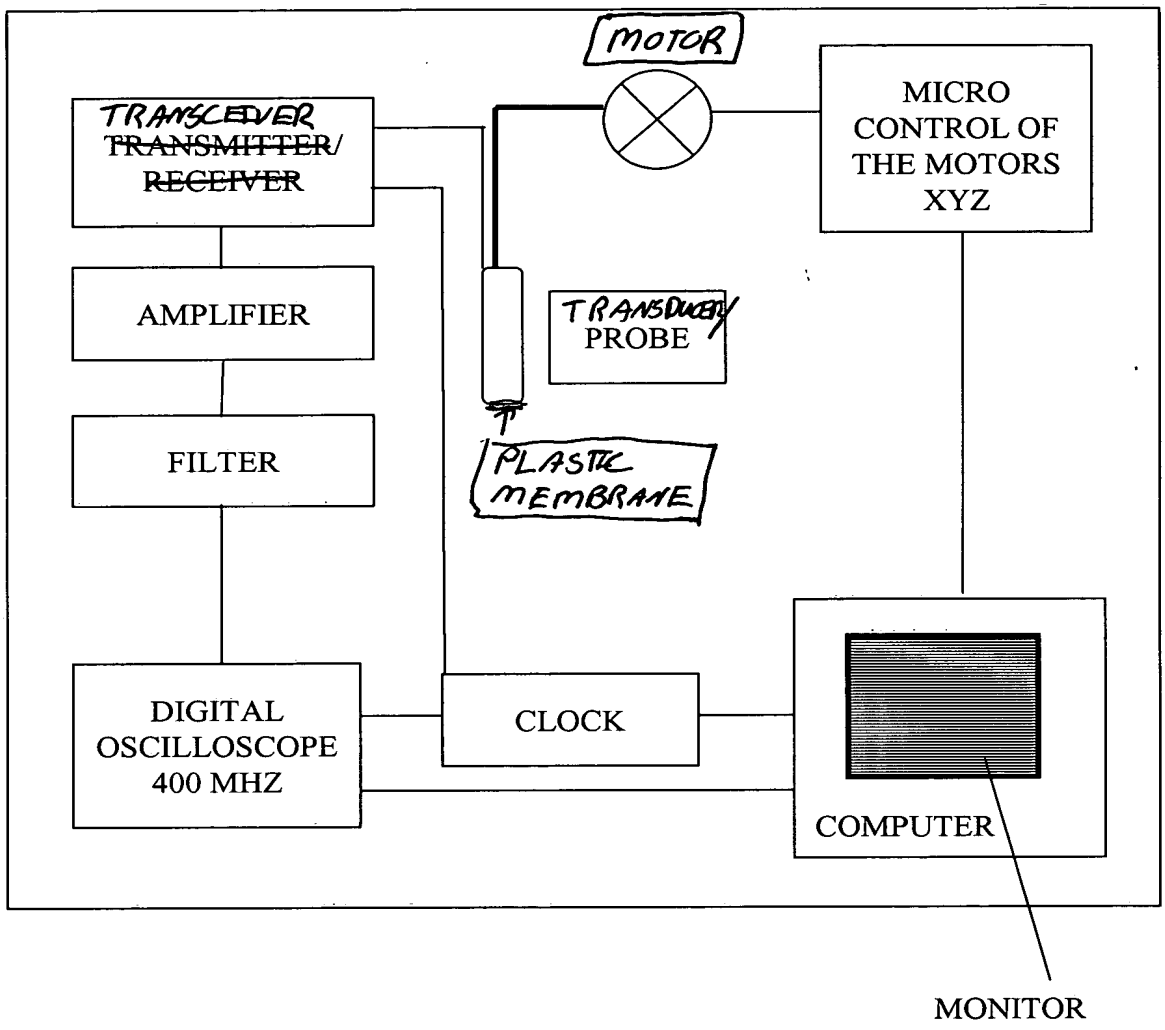

FIG. 6